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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,546	04/25/2000	ELLIOTT BENNETT-GUERRERO	08213/007001	6875

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 02/25/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,546

Applicant(s)

BENNETT-GUERRERO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13December2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44,47-49,52-59,61-64,66-69,72-76 and 78-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44,47-49,52-59,61-64,66-69,72-76 and 78-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,11,15</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Response to Office Action, received 13 December 2001, paper #14, is acknowledged.

Claims 45, 46, 50, 51, 60, 65, 70, 71, and 77 have been canceled without prejudice.

Claims 44, 47-49, 52-55, 57-59, 61, 64, 66-69, 72, 73, 75, 78-85, and 88-93 have been amended.

New claims 101-111 have been added.

2. Currently, claims 44, 47-49, 52-59, 61-64, 66-69, 72-76, and 78-111 are pending and under consideration.

Rejections Moot/Withdrawn

3. The rejection of claim 45 under 35 U.S.C. 112, second paragraph, number of bacteria, is moot in light of the cancellation of the claim.

4. The rejection of claims 45, 46, 50, 51, 60, 65, 70, 71, and 77 under 35 U.S.C. 112, second paragraph, "comprising a bacterium, is moot in light of the cancellation of the claims.

5. The rejection of claims 45, 46, 50, 51, 60, 65, 70, 71, and 77 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment of animals, is moot in light of the cancellation of the claims.

6. The rejection of claims 45 and 60, under 35 U.S.C. 103(a) as being unpatentable over Johns et al (*Inf. Immun.*, 17(1):9-15, 1977) in view of Gram et al (U.S. Pat. No. 5,858,728) is moot in light of the cancellation of the claims.

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7. The rejection of claims 47-49, 52-59, 61-64, 66-69, 72-76, and 78-100 under 35 U.S.C. 112, second paragraph, "comprising a bacterium", is withdrawn.

8. The rejection of claims 44, 47-49, 59, 61-64, 66-69, 72-76, 84-89, 93, and 95-100 under 35 U.S.C. 103(a) as being unpatentable over Johns et al (*Inf. Immun.*, 17(1):9-15, 1977) in view of Gram et al (U.S.Pat.No. 5,858,728) is withdrawn.

Applicants argue that Johns et al does not teach or suggest rough complete core mutants as an active vaccine. Applicants argue that Gram et al do not correct the inadequacies of Johns et al but teach only production of monoclonal antibodies.

The examiner has considered applicants' arguments, and finds them persuasive.

Rejection Maintained

9. The rejection of claims 44, 47-49, 52-59, 61-64, 66-69, 72-76, 78-96, 99, and 100 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment of animals, is maintained.

Applicants argue that the specification of the international publication for this U.S. national phase application (WO98/09988) provides adequate information to enable the instant claims. Applicants have provided a reference which indicates that the teachings in the specification are enabling, resulting in the claimed invention.

The examiner has considered applicants' argument, but does not find it persuasive. The scope of the instant claims encompasses cocktails of rough, complete-core LPS from ≥ 2 bacterial strains selected from: *E. coli*, *Pseudomonas*, *Klebsiella*, *Salmonella*, and *Bacteroides*, whereing the LPS may comprise whole killed whole cells.

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The reference which applicants provided for support of their argument utilizes only two specific compositions, either a liposomal composition consisting only of purified *E. coli* K-12 LPS or a cocktail of purified LPS from only *E. coli* K-12, *E. coli* R1, *P. aeruginosa* PAC608, and *B. fragilis* LPS. The reference does not provide any guidance or working examples of compositions commensurate with the scope of the instant, i.e., methods of reducing adverse effects of endotoxin by administration of *Salmonella* and *Klebsiella* either as purified LPS or whole killed cells. In addition, the instant specification teaches away from whole killed cells which are killed by other than heat or formaldehyde, i.e., page 14, lines 13-14 "It is desirable to avoid bacterial killing methods which can alter the core."

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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12. Claim 111 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "the method of claim 44 of 64".

13. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that "the other of said bacterial strains". However, it is unclear what this means because the claim depends from claim 44 which recites "at least two" organisms. In the case of the compositions comprising four organisms, which is "the other"

14. Claims 101-111 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of animals by administration of purified rough, complete-core LPS incorporated into liposomes, does not reasonably provide enablement for treating animals by administering whole killed cells or merely purified LPS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of reducing adverse effects of endotoxin in animals by administration compositions comprising rough, complete-core LPS antigens. Both the instant specification and the cited reference discussed above provide examples only of purified rough, complete-core LPS incorporated into liposomes. The cited reference is silent

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concerning whole cell compositions and the instant specification provides merely speculation concerning whole cell compositions. The open language of the instant claims "composition comprising LPS antigen" reads on whole cells.

15. Claims 97 and 98 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the actual quantitation steps. The claims merely state that the quantitation is by staining. However, the specification teaches an involved procedure utilizing desktop scanners, photoshop, and a computer software program.

Conclusion

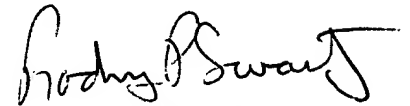
16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

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February 25, 2002